DUOCARE- ivermectin and praziquantel paste Farnam Companies Inc

DuoCare(tm) Paste (ivermectin 1.87%/praziquantel 23.38%)

INDICATIONS:

Consult your veterinarian for the assistance in the diagnosis, treatment, and control of parasitism. DuoCareTM (ivermectin 1.87%/praziquantel 23.38%) Paste is indicated for the treatment and control of the following parasites in horses over 5 months of age:

Tapeworms Anoplocephala perfoliata; Large Strongyles (adults) – Strongylus vulgaris (also early forms in blood vessels), S. edentatus (also tissue stages), S. equinus, Triodontophorus spp. including T. brevicauda and T. serratus, and Craterostomum acuticaudatum; Small Strongyles (adults, including those resistant to some benzimidazole class compounds) – Coronocyclus spp. including C. coronatus, C. labiatus and C. labratus; Cyathostomum spp. including C. catinatum and C. pateratum; Cylicocyclus spp. including C. insigne, C.leptostomum, C. nassatus and C. brevicapsulatus; Cylicodontophorus spp.; Cylicostephanus spp. including C. calicatus, C. goldi, C. longibursatus and C. minutus, and Petrovinema poculatum; Small Strongyles – Fourth-stage larvae; Pinworms (adults and fourth-stage larvae) – Oxyuris equi; Ascarids (adults and third- and fourth-stage larvae) – Parascaris equorum; Hairworms (adults) – Trichostrongylus axei; Large-mouth Stomach Worms (adults) – Habronema muscae; Bots (oral and gastric stages) – Gasterophilus spp. including G. intestinalis and G. nasalis; Lungworms (adults and fourth-stage larvae) – Dictyocaulus arnfieldi; Intestinal Threadworms (adults) – Strongyloides westeri; SummerSores caused by Habronema and Draschia spp. cutaneous thirdstage larvae; Dermatitis caused by neck threadworm microfilariae, Onchocerca sp.

DOSAGE AND ADMINISTRATION:

This syringe contains sufficient paste to treat one 1250-lb horse at the recommended dose rate of 91 mcg ivermectin per lb (200 mcg/

kg) and 1.14 mg praziquantel per lb (2.5 mg/kg) of body weight. Each weight marking on the syringe plunger delivers enough paste to treat 250 lb of body weight. (1) Turn the threaded ring on the plunger to the prescribed weight marking. (2) Make sure that the horse's mouth contains no feed. (3) Remove the cover from the tip of the syringe twisting gently while pulling the cap off. (4) Insert the syringe tip into the horse's mouth at the space between the teeth. Take care not to move the adjustment ring on the plunger while gripping the syringe. (5) Depress the plunger as far as it will go, depositing paste on the back of the tongue. (6) Immediately raise the horse's head for a few seconds after dosing.

PARASITE CONTROL PROGRAM:

All horses should be included in a regular parasite control program with particular attention being paid to mares, foals, and yearlings.

Consult your veterinarian to determine what product is most appropriate for foals less than 5 months of age. Foals can be treated initially with DuoCareTM (ivermectin 1.87%/praziquantel 23.38%) Paste at 5 months of age, and routine treatment repeated as appropriate. Consult your veterinarian for a control program to meet your specific needs.

DuoCare™ (ivermectin 1.87%/praziquantel 23.38%) Paste effectively controls gastrointestinal nematodes, cestodes and bots of horses. Regular treatment will reduce the chances of verminous arteritis caused by *Strongylus vulgaris*.

PRODUCT ADVANTAGES:

Broad-spectrum Control- DuoCareTM (ivermectin 1.87%/praziquantel 23.38%) Paste kills important internal parasites, including tapeworms,

bots and the arterial stages of *S. vulgaris*, with a single dose. DuoCareTM (ivermectin 1.87%/praziquantel 23.38%) Paste contains two potent antiparasitic agents that are neither benzimidazoles nor organophosphates.

ANIMAL SAFETY:

DuoCareTM (ivermectin 1.87%/praziquantel 23.38%) Paste may be used in horses 5 months of age and older. DuoCareTM (ivermectin 1.87%/praziquantel 23.38%) Paste has not been tested in foals younger than five months of age, in pregnant mares or breeding stallions. In a safety study in which 5 to 6 month old foals were treated at 1, 3 and 5 times the maximum recommended dose for 4 consecutive days, a colic event was observed on post-treatment day 5 in one foal administered the 3x dose. This event resolved without treatment and no other foals were affected.

WARNING:

Do not use in horses intended for human consumption.

HUMAN WARNINGS:

Not for use in humans. Keep this and all drugs out of the reach of children. Refrain from eating or smoking when handling. Wash hands after use. Avoid contact with eyes. The Material Safety Data Sheet (MSDS) contains more detailed occupational safety information. To report adverse reactions in users, to obtain more information, or to obtain a MSDS, contact Farnam Companies, Inc. at 1-800-234-2269.

PRECAUTIONS:

DuoCare™ (ivermectin 1.87%/praziquantel 23.38%) Paste has been formulated specifically for use in horses only. This product should not be used in other animal species as severe adverse reactions, including fatalities in dogs, may result. The safety of DuoCare™ (ivermectin 1.87%/praziquantel 23.38%) Paste in horses used for breeding purposes, pregnant, or lactating mares has not been demonstrated.

ENVIRONMENTAL WARNINGS:

Ivermectin and excreted ivermectin residues may adversely affect aquatic organisms. Do not contaminate ground or surface water. Dispose of the syringe in an approved landfill or by incineration.

INFORMATION FOR HORSE OWNERS:

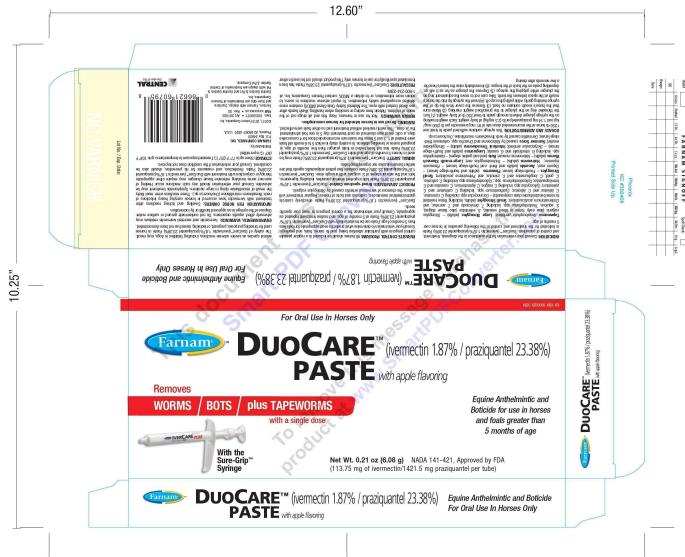
Swelling and itching reactions after treatment with ivermectin have occurred in horses carrying heavy infections of neck threadworm microfilariae (*Onchocerca* sp.). These reactions were most likely the result of microfilariae dying in large numbers. Symptomatic treatment may be advisable. Consult your veterinarian should any such reactions occur. Healing of summer sores involving extensive tissue changes may require other appropriate therapy in conjunction with treatment with DuoCareTM (ivermectin 1.87%/praziquantel 23.38%) Paste. Reinfection, and measures for its prevention, should also be considered. Consult your veterinarian if the condition does not improve.

STORAGE:

Store up to 77° F (25° C). Transient exposure to temperatures up to 104° F (40° C) is permitted.

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DUOCARE

paste paste

Product Information			
Product Type	OTC ANIMAL DRUG	Item Code (Source)	NDC:17135-401
Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
IVERMECTIN (UNII: 8883YP2R6D) (IVERMECTIN - UNII:8883YP2R6D)	IVERMECTIN	113.75 mg in 6.08 g
PRAZIQUANTEL (UNII: 6490C9U457) (PRAZIQUANTEL - UNII:6490C9U457)	PRAZIQUANTEL	1421.5 mg in 6.08 g

Product Characteristics			
Color	white	Score	
Shape		Size	
Flavor	APPLE	Imprint Code	
Contains			

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:17135-401-21	24 in 1 CASE		
1	NDC:17135-401-22	1 in 1 BOX, UNIT-DOSE		
1	NDC:17135-401-23	6.08 g in 1 SYRINGE, PLASTIC		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
NADA	NADA141421	0 4/2 1/20 15		

Labeler - Farnam Companies Inc (008399933)

Registrant - Merial (501417471)

Establishment			
Name	Address	ID/FEI	Business Operations
Med-Pharmex Inc		025353699	manufacture, pack

Establishment			
Name	Address	ID/FEI	Business Operations
Cipla Ltd		916940208	api manufacture

Establishment			
Name	Address	ID/FEI	Business Operations
Zhejiang Hisun Pharmaceutical Co Ltd		654211754	api manufacture

Revised: 4/2015 Farnam Companies Inc